

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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DR. PAULA SMALL,

Plaintiff,

- against -

NOBEL BIOCARE USA, LLC and IMPLANT  
DIRECT MFG. LLC d/b/a IMPLANT DIRECT,  
LLC,

Defendants.  
-----X

NAOMI REICE BUCHWALD  
UNITED STATES DISTRICT JUDGE

**MEMORANDUM AND ORDER**

05 Civ. 3225 (NRB)  
06 Civ. 683 (NRB)

Plaintiff Dr. Paula Small ("Small") brings these patent infringement actions against defendants Nobel Biocare USA, LLC ("Nobel") and Implant Direct Mfg. LLC, d/b/a Implant Direct, LLC ("Implant Direct"), alleging their products infringed U.S. Patent Nos. 5,580,246 (the "'246 Patent") and RE38,945 (the "'945 Patent" or "reissue patent"). Both patents describe a method to rehabilitate a damaged dental implant and an improved dental implant design to prevent the crown mounted upon the implant from rotating.

Presently before the Court are three motions for summary judgment. With respect to the '246 Patent, Nobel moves for summary judgment on the grounds that an invention embodying the asserted claims was on sale and in public use more than one year

before the patent application was filed. With respect to the '945 Patent, Nobel moves for summary judgment asserting the invalidity of the asserted claims on three separate bases: they allegedly fail to comply with the written description requirement, violate the rule against reissue recapture, and anticipate the prior art. Implant Direct joins that motion and moves for summary judgment on non-infringement grounds, arguing that its accused products do not embody all of the asserted claims.

For the reasons set forth herein, we grant Nobel's motion for summary judgment seeking the invalidity of the '246 Patent claims, finding that an invention embodying those claims was in public use more than one year before filing. We further grant Nobel's motion for summary judgment seeking the invalidity of the asserted '945 Patent claims on the ground that the patent lacked an adequate written description of those claims. Alternatively, we conclude that the '945 reissue application did not provide sufficient notice of the asserted claims within the requisite two-year statutory period. Finally, because we invalidate the '945 Patent claims asserted in these actions, we grant Implant Direct's motion for summary judgment due to non-infringement of the '945 Patent as well.

## BACKGROUND<sup>1</sup>

### I. Factual Background

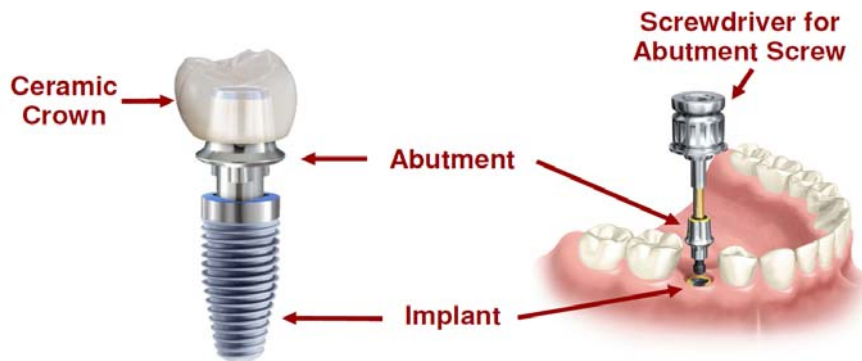
#### A. Dental Implants

Dental implants are metal screws inserted in a patient's jaw bone to serve as anchors for prosthetic teeth. An oral surgeon typically installs an implant by making an incision in the patient's gum to expose the jaw bone, drilling a hole into the jaw bone, and screwing the implant into the hole so that its "proximal," or top, end sits level to the gum surface. The implant eventually integrates into the patient's jaw bone during a process known as "osseointegration," after which the gum is reopened to expose the implant for placement of the prosthetic

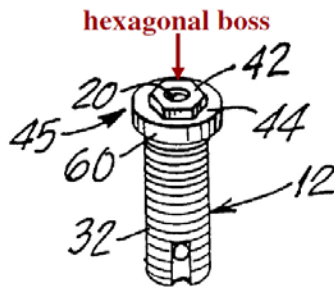
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<sup>1</sup> We assume familiarity with the background of these cases as discussed in this Court's prior decisions. See Small v. Nobel Biocare USA, LLC, et al., Nos. 05 Civ. 3225 (RJH), 06 Civ. 683 (RJH), 2011 WL 3586470 (S.D.N.Y. Aug. 11, 2011); Small v. Nobel Biocare USA, LLC, et al., Nos. 05 Civ. 3225 (RJH), 06 Civ. 683 (RJH), 2012 WL 952396 (S.D.N.Y. Mar. 21, 2012). The background provided herein is not intended to be comprehensive or to provide a construction of any disputed claim terms. Rather, it is intended only to highlight those facts pertinent to the instant motions. Such facts are derived from the undisputed or improperly disputed facts in the parties' Statements of Material Facts pursuant to Local Rule 56.1, the uncontroverted record evidence, and this Court's prior decisions. Accordingly, we cite throughout to Nobel's Statement of Undisputed Facts in Support of its Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,580,246 ("Nobel '246 56.1"), Dr. Paula Small's Response to Nobel's Statement Pursuant to Local Rule 56.1 in Support of its Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,580,246 ("Small '246 56.1"), the Declaration of Baraa Kahf in Support of Nobel's Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,580,246 ("Kahf Decl."), Nobel's Statement of Undisputed Facts in Support of its Motion for Summary Judgment of Invalidity of U.S. Patent No. RE38,945 ("Nobel '945 56.1"), Dr. Paula Small's Response to Nobel's Statement Pursuant to Local Rule 56.1 ("Pl. 56.1"), the Declaration of Sean M. Murray in Support of Nobel's Motion for Summary Judgment of Invalidity of U.S. Patent No. RE38,945 ("Murray Decl."), and the Declaration of Robert Bugg in Support of Small's Opposition to Nobel's Motion for Summary Judgment of Invalidity of U.S. Patent No. RE38,945 ("Bugg Decl.).

tooth. The prosthesis, usually a ceramic crown, is then mounted on a component part called an "abutment," which in turn is attached to the implant using a small "abutment screw." These components are shown in the diagram below.

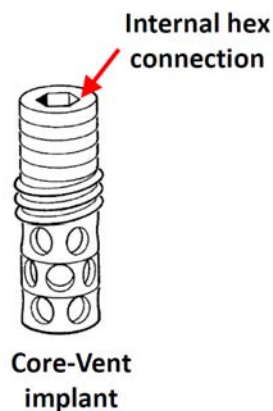


Dental implants are generally divided into two categories based on the mechanism by which they connect to an abutment. External connection implants have a protruding hexagonal head, or "boss," at their top end. The boss serves two functions: First, it attaches to the wrench or driver used to screw the implant into the patient's jaw bone; and second, it is received in a matching hexagonal socket in the abutment, which is intended to secure the abutment to the implant. (See '945 Patent, Murray Decl. Ex. 3, at 4:54-61, Fig. 2.) The prototypical external connection or "bossed" implant, commonly referred to as the "Branemark-type" implant, is shown in the diagram below.



**'945 Patent Fig. 2  
(Branemark-Type Implant)**

By contrast, internal connection implants are designed to receive a projecting feature on the abutment, such that the implant contains a socket or "recess," rather than a boss, at its proximal end. (See Murray Decl. Ex. 4, at 78.) In this way, internal connection implants reverse the features of external connection or bossed implants: instead of the implant having a projection and the abutment a recess, the implant has the recess and the abutment has the projection. An example of an internal connection or "recessed" implant, Nobel's Core-Vent implant, is shown in the diagram below.



## B. The '246 Patent

### 1. Small's 1993 Clinical Work

In October 1993, while working at the N.Y.U. College of Dentistry's dental clinic, Small treated a patient whose crown had begun rotating on top of a previously-inserted Branemark-type implant. (Nobel '246 56.1 ¶ 5; Pl. '246 56.1 ¶ 5; see Small Dep., Murray Decl. Ex. 5, at 77:15-17, 78:20-24.) Upon removing the patient's crown, Small observed that the hexagonal boss on the top of the implant had become "stripped," or rounded, thereby diminishing the implant's ability to stabilize the crown and causing it to loosen. (Small Dep., Murray Decl. Ex. 5, at 79:12-17; see '246 Patent, Murray Decl. Ex. 1, at Col. 2:12-28, 35-40.)

To avoid having to remove the implant from the patient's jaw, which would have necessitated a rather brutal procedure by which the implant would have to be drilled out of the bone, Small decided to modify the implant in vivo by drilling "slots," or indentations, into the top of the implant. (Nobel '246 56.1 ¶ 6; Pl. '246 56.1 ¶ 6; Small Dep., Murray Decl. Ex. 5, at 97:3-99:8.) The patient consented to the proposed procedure, but did not fill out any particular waiver beyond the clinic's standard consent form. (Nobel '246 56.1 ¶ 9; Small '246 56.1 ¶ 9; Small Dep., Murray Decl. Ex. 5, at 104:6-10.) No confidentiality

restrictions of any kind were placed upon the patient regarding the implant modification. (Small Dep., Murray Decl. Ex. 5, at 104:11-25, 124:2-10.) Moreover, although the patient paid for the procedure according to the clinic's standard fee-for-services payment structure, the patient did not render payment specifically for the slotted modification. (Nobel '246 56.1 ¶ 10; Small '246 56.1 ¶ 10; Small Dep., Murray Decl. Ex. 5, at 126:6-22.)

While a graduate student assisting the procedure took photographs, Small drilled two slots into the top of the implant's hexagonal boss. (Nobel '246 56.1 ¶ 6; Pl. '246 56.1 ¶ 6; Small Dep., Murray Decl. Ex. 5, at 97:3-99:8, 111:18-113:24; see id. Ex. 4 (photocopy reproductions of slides).) She did not measure the depth of the slots.<sup>2</sup> (Small '246 56.1 ¶ 6; Small Dep., Murray Decl. Ex. 5, at 101:18-24.) She then made dental impressions of the patient's mouth which she gave to a lab technician, Leonard Marotta,<sup>3</sup> who used them to create a custom crown with matching projections that would engage the

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<sup>2</sup> In her deposition, Small testified that she was not trying to achieve any particular slot depth when she manually drilled the indentations into the top of her patient's implant. (See Small Dep., Murray Decl. Ex. 5, at 101:18-24.) In fact, when shown slides that had been taken during the procedure, Small observed that she had "engaged the hex[agonal boss] on one side a little bit more than the other," such that one slot appeared to have been drilled completely through the implant's flange and the other only partially through it. (Id. at 100:2-3, 17-19.)

<sup>3</sup> Marotta is also listed as a co-inventor on Small's '246 Patent application. ('246 Patent, Murray Decl. Ex. 1, at 1.)

slots. (Small Dep., Murray Decl. Ex. 5, at 101:25-102:19, 102:20-103:16, 105:1-8, 106:2-12, 118:4-8.)

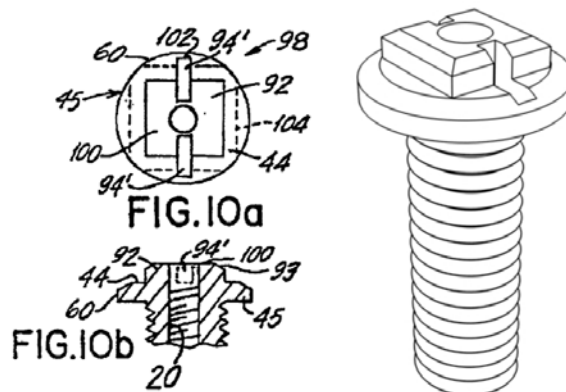
In November 1993, Small reopened the patient's incision and attached the custom-made crown to the implant. (Id. at 123:11-124:17.) She observed that the modified implant design served its intended purpose, that is, to match the projections in the crown and prevent it from rotating. (Id. at 116:6-12, 19-20, 116:23-117:1.)

Subsequent to the filing of her initial patent application, Small performed similar in vivo modifications on two other previously-inserted Branemark-type implants. (Id. at 131:8-22.) However, she conducted no further testing of the implants' design, nor did she create a prototype of a slotted, bossed implant. (Id. at 163:22-164:1, 204:6-12; see also Marotta Dep., Murray Decl. Ex. 6, at 104:13-15.)

## **2. '246 Patent Prosecution**

On January 30, 1995, Small filed her first patent application directed to slotted dental implants. ('246 Patent, Murray Decl. Ex. 1.) The initial application disclosed both a method to rehabilitate a damaged implant in a patient's mouth and an improved implant with slots to better resist rotation of the abutment. (Id. at col. 2:55-59.) The 1995 application issued as the '246 Patent on December 3, 1996.

As issued, the '246 Patent discloses no written description or drawings directed to an implant with recesses rather than bosses. Rather, as shown in the example below, its specification describes only implants with bosses, and each of its claims requires an external connection. (Id. at Claims 1-22.)



### 3. '246 Patent Claims at Issue

Small asserts Claims 11, 14, and 15 of the '246 Patent against Nobel.<sup>4</sup> Claim 11, an independent claim, recites:

A dental implant for insertion in the jaw bone of a patient, comprising: an elongated body having a longitudinal axis and a proximal surface generally transverse to said longitudinal axis, said proximal surface is a portion of a radially extending flange on said body, said flange having thickness, a boss

<sup>4</sup> As stated in footnote 1, supra, the relevant background pertaining to the construction of the asserted claims is set forth in detail in Judge Holwell's August 11, 2011 claim construction opinion and in this Court's March 21, 2012 reconsideration decision. See Small v. Nobel Biocare USA, LLC, et al., Nos. 05 Civ. 3225 (RJH), 06 Civ. 683 (RJH), 2011 WL 3586470 (S.D.N.Y. Aug. 11, 2011); Small v. Nobel Biocare USA, LLC, et al., Nos. 05 Civ. 3225 (RJH), 06 Civ. 683 (RJH), 2012 WL 952396 (S.D.N.Y. Mar. 21, 2012). We assume familiarity with the terminology and constructions discussed therein.

extending from said proximal surface, said boss having a transverse face and a non-round cross section as viewed transversely along said axis, and an axial hole in said body, at least one slot penetrating at least one of said proximal surface and said transverse face of said implant and terminating within the thickness of said flange.

(Id. at col. 13:9-18.)

Claims 14 and 15, which depend from Claim 11, require additional features beyond those disclosed above. In particular, Claim 14 describes a dental implant "as in claim 11, wherein said non-round cross section is polygonal." (Id. at col. 13:27-28.) Claim 15 describes an implant "as in claim 11, wherein said axial hole is threaded." (Id. at col. 13:29-30.)

### **C. The '590 Patent**

On December 2, 1996, just one day before the '246 Patent issued, Small filed a continuation-in-part application<sup>5</sup> (the "1996 application"), which relied in part on the '246 Patent as well as new text and drawings describing additional features. (1996 Appl., Murray Decl. Ex. 7, at 31:11-36:17, 37:17-24, Figs. 16-19m.) The 1996 application, which would eventually issue in part as the '590 Patent, disclosed some claims directed to

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<sup>5</sup> A "continuation-in-part" application gives the patentee the opportunity to disclose and claim subject matter not disclosed in the original patent (provided there is inventorship overlap between the continuing application and the original application), while claiming priority based on the filing date of the original application. It allows the inventor to claim additional enhancements developed after the original patent application was filed without forfeiting the benefit of the earlier filing date. See 37 C.F.R. § 1.53(b)(2).

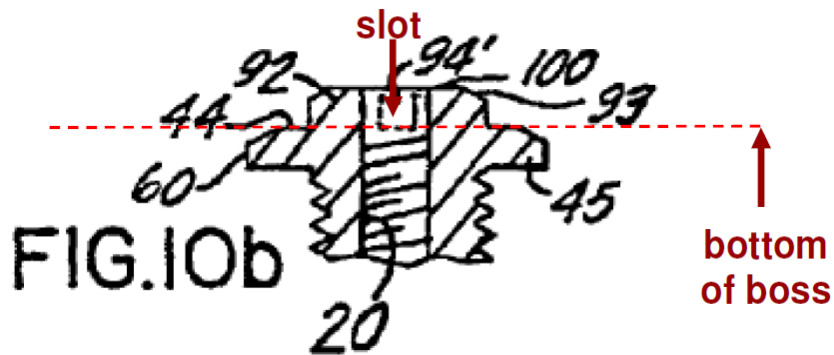
bossed implants (see '590 Patent Appl. Claims 1-11, Murray Decl. Ex. 7, at 39-42) and some directed to recessed implants (see '590 Patent Appl. Claims 12-16, id.). (Def. 56.1 ¶ 2; Pl. 56.1 ¶ 2.)

However, the 1996 application's specification was directed almost exclusively to bossed implants. Its only reference to recessed implants appears in the penultimate paragraph of the written description, which states that the bosses shown in the patent's figures could be "reversed" and formed as recesses:

It should also be understood that a reversal of features is intended to fall within the inventions [sic] scope. Thus any boss cross-section which has been described as protruding from the flange surface 44 may also be formed (and viewed in the Figures) as a recess in the surface 44. In such a construction the mating crown or abutment is fabricated with a correspondingly shaped protrusion (or protrusions) that seat(s) in the recess (or recesses).

('590 Patent Appl., Murray Decl. Ex. 7, at 37:17-24.)

Moreover, and of particular importance to the instant motions, the 1996 application's specification did not depict or describe slots of any particular depth. As shown below, it contained only one figure showing visible slot depth, which depicts a bossed implant with slots that extend all the way down to the bottom of the boss.



Indeed, the specification contained just three textual references to slot depth, none of which indicated that any particular depth was required:

The slot 94' may penetrate in depth into the upper surface 100 of the boss 92 . . . . On the other hand, the slot depth may be extended (not shown) substantially, even into the flange 45, that is, below the surface 44 of the flange 45.

(Id. at 27:6-11.) Nor did the specification place any limit, minimum or maximum, on the depth of the slots:

As with the implant 98, the slot 94' can penetrate the boss 92 to various depths and may extend to and penetrate into the flange 45.

(Id. at 28:3-6.) In fact, the specification described slot depth as a feature selectable by the manufacturer upon production:

In FIG. 13, an implant 107 includes a generally triangular boss 113 that is penetrated by slots 115, 116 of extended length and selectable (in manufacture) depth that pass through an apex of the triangle.

(Id. at 28:16-19.)

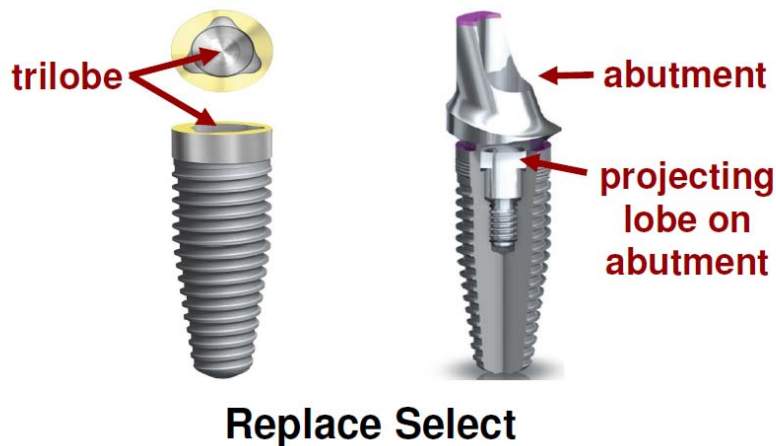
# **1. Cancellation of the '590 Patent's Recess Claims**

On October 28, 1997, the Patent Office rejected Claims 12-16 of the 1996 Application, the claims directed to a recessed implant, as anticipated by the prior art. (October 28, 1997 Office Action, Murray Decl. Ex. 8, at 2-3.) Specifically, the patent examiner concluded that the recessed claims were anticipated by the Gersberg, Symington, and Kiernan patents, all of which disclosed recessed implants with slots. (Id.)

In response, Small did not seek to amend her recessed claims, nor did she argue that she was in fact entitled to claim recessed implants despite the prior art. (See February 6, 1998 Amendment, Murray Decl. Ex. 9, at 1-3.) Instead, she simply cancelled all of the claims directed to recessed implants. (See id.) Thus, when the '590 Patent issued on September 23, 1998, it contained only claims to slotted implants with a boss. (Def. 56.1 ¶ 2; Pl. 56.1 ¶ 2; see '590 Patent, Murray Decl. Ex. 2, at Claims 1-11.)

#### **D. The Launch of Nobel's Replace Select Implant**

In 1999, Nobel launched its Replace Select implant, an internal connection implant with a recess and three lobes (the "trilobe" feature) that extend part way down the recess walls. (Hurson Decl. ¶ 6.) The Replace Select implant is shown in the figure below.



On September 29, 1999, Nobel applied for a patent directed to aspects of the Replace Select implant. U.S. Patent No. 6,733,291 (the “’291 Patent”) issued on May 11, 2004. (See Nobel’s Submission of Documents and Legal Authority Discussed in the June 18, 2013 Oral Argument of Nobel’s Motion for Summary Judgment of Invalidity of U.S. Patent No. RE38,945, dkt. no. 328, at 2; id. App’x. 2, at 1.) Small’s ’246 and ’590 Patents were considered during the prosecution of Nobel’s ’291 Patent and are listed in its “References Cited” section. (Id. App’x 2, at 1.)

The Replace Select implant was immediately successful in the marketplace and soon became one of the leading dental implant models in the industry. (Hurson Decl. ¶ 6.)

#### **E. The ’945 Reissue Patent**

On September 22, 2000, just one day before the close of the two-year statutory period for reissue applications, Small

petitioned the Patent Office to reissue the '590 Patent with broader claims. (See '945 Patent, Murray Decl. Ex. 3, at 1.) Like her 1996 continuation-in-part application, the reissue application claimed priority to the filing date of the initial '246 Patent. (Id.)

However, Small failed to include in her application the required declaration specifying at least one error to be corrected upon reissue. Thus, on October 12, 2000, the Patent Office issued a Notice to File Missing Parts indicating that the "oath or declaration" was missing from the reissue application. Small filed a supplemental declaration with the Patent Office on January 19, 2001, but it contained no description of the purported error to be corrected. The Patent Office rejected her declaration as a result, noting that it, too, "fail[ed] to identify at least one error which is relied upon to support the reissue application." (See Murray Decl. Ex. 10, at 5 (referring to July 22, 2003 Office Action).)

In her October 22, 2003 response, Small finally provided a complete declaration, which asserted that the error warranting reissue of the '590 Patent was her "[f]ailure to broadly claim the 'boss' as set forth in claim 15." (Murray Decl. Ex. 11.) The accompanying proposed amended claims, filed the same day,

were directed only to bossed implants. (See Murray Decl. Ex. 10, at 3-4.)

#### **1. 2004 Amendment to the Reissue Patent: Addition of Recess Claims**

It was not until October 28, 2004 - more than four years after petitioning for reissue and more than six years after the '590 Patent issued - that Small added new claims directed to recessed implants. (October 28, 2004 Preliminary Amendment, Murray Decl. Ex. 12, at 2 (proposing new claim 16).) The proposed claims, which eventually reissued as Claims 14-22, required, inter alia, "a recess extending into [the] proximal surface."<sup>6</sup> (Small '945 56.1 ¶ 3; '945 Patent, Murray Decl. Ex. 3.)

Because prior patents had disclosed slots which extend down to the bottom wall of the recess, the Patent Office once again concluded that Small's recessed claims were anticipated by the prior art and rejected them. (See January 14, 2005 Office Action, Murray Decl. Ex. 14, at 2-4.) Thus, following the Examiner's suggestion, Small subsequently amended her proposed recessed claims to specify that the slots extend "only part way down" the side surfaces of the recess. (See May 5, 2005 Response to January 14, 2005 Office Action, Murray Decl. Ex. 15,

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<sup>6</sup> Small did not amend the '590 Patent's specification at any point during her '945 Patent reissue proceeding. Thus, the '590 Patent application's specification became the specification of the '945 Reissue Patent.

at 4-5.) The Examiner then issued a Notice of Allowance permitting Small's amendment to her recess claims and closing prosecution of the merits of her reissue application. (See Notice of Allowance, Murray Decl. Ex. 16, at 1.) There is no evidence that the Examiner considered Nobel's '291 Patent before issuing the allowance. (Id.)

After Small's patent reissued as the '945 Patent on January 24, 2006, she immediately brought suit against Nobel, claiming that the Replace Select implant it introduced in 1999 infringed the recessed claims she added in 2004. (See Compl., Jan. 30, 2006 (dkt. no. 1).)

## **2. Relevant '945 Patent Claims**

Small has asserted Claims 14-20 and 22 of the '945 Patent against Nobel and Implant Direct. Independent Claim 14 recites:

A dental implant for insertion in the jaw bone of a patient, comprising:

an elongated body having a longitudinal axis and an axial hole, said body having a proximal end that terminates in a proximal surface that is generally transverse to said longitudinal axis,

a recess extending into said proximal surface, said recess having a bottom wall including an opening that communicates with said axial hole, and smooth, generally axial extended side surfaces, and

a plurality of slots penetrating said proximal surface and axially extending only part way down said side surfaces toward said bottom wall, said slots being adapted to engage an insertion device or at least one protrusion of a dental prosthesis or abutment so as to fix the position of the abutment or crown relative to said implant.

('945 Patent, Murray Decl. Ex. 3, at col. 16:10-25.) Claims 15-20 and 22, which depend from Claim 14, require additional features as follows:

15. A dental implant as in claim 16, wherein said body includes an enlarged end.

16. A dental implant as in claim 16, wherein said recess includes a beveled surface.

17. A dental implant as in claim 16, wherein said elongated body includes screw threads around its exterior beneath said enlarged end, and a diameter of said enlarged end is greater than a diameter of said screw threads.

18. A dental implant as in claim 19, wherein said enlarged end includes a circular flange.

19. A dental implant as in claim 16, wherein said recess has curved side surfaces.

20. A dental implant as in claim 16, wherein said slots have flat sides that intersect in substantially right angles.

22. A dental implant as in claim 16, wherein said axial hole is threaded.

(Id. at col. 16:26-39, 41-42.)

## **II. Relevant Procedural History<sup>7</sup>**

Nobel moved for summary judgment of the invalidity of the '246 Patent on November 19, 2012 (dkt. no. 144) and for summary judgment of the invalidity of the '945 Patent on November 29, 2012 (dkt no. 286). Implant Direct moved for summary judgment on December 10, 2012 (dkt. no. 292). The Court heard oral

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<sup>7</sup> The history of these actions is discussed at length in our decision denying Small's motion for reconsideration. See 2012 WL 952396, at \*1. We assume familiarity with the procedural background contained therein.

argument on all motions for summary judgment on June 18, 2013 ("oral argument").<sup>8</sup>

## DISCUSSION

### I. Legal Standards

A motion for summary judgment is appropriately granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In this context, "[a] fact is 'material' when it might affect the outcome of the suit under governing law," and "[a]n issue of fact is 'genuine' if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 202 (2d Cir. 2007) (internal quotation marks omitted). When making this determination, "we are required to resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought." Gorzynski v. JetBlue Airways Corp., 596 F.3d 93, 101 (2d Cir. 2010) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)).

On a motion for summary judgment, "[t]he moving party bears the initial burden of demonstrating 'the absence of a genuine issue of material fact.'" FDIC v. Great Am. Ins. Co., 607 F.3d 288, 292 (2d Cir. 2010) (quoting Celotex Corp. v. Catrett, 477

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<sup>8</sup> References preceded by "Tr." refer to the transcript of oral argument.

U.S. 317, 323 (1986)). Where that burden is carried, the nonmoving party "must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." Id. (citing Anderson, 477 U.S. at 249). The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts and may not rely on conclusory allegations or unsubstantiated speculation." Brown v. Eli Lilly & Co., 654 F.3d 347, 358 (2d Cir. 2011) (internal quotation marks and citation omitted).

Because a U.S. patent is presumed to be valid, a movant must support its contention of invalidity with clear and convincing evidence. See Young v. Lumenis, Inc., 492 F.3d 1336, 1345 (Fed. Cir. 2007). A particular patent claim may be invalidated upon such a showing, the sufficiency of which is a question of law. See Aero Prods. Int'l, Inc. v. Intex Recreation Corp., 466 F.3d 1000, 1015-16 (Fed. Cir. 2006).

## **II. Patent Sufficiency Requirements Under 35 U.S.C. § 112**

Section 112 of title 35 of the United States Code contains three requirements for the specification of a patent: a written description of the claimed invention; enablement to make and use the invention; and a description of the best mode of carrying out the invention. 35 U.S.C. § 112; see Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1345-47 (Fed. Cir. 2010).

Section 112 further limits the ability of claims to be too open-ended or indefinite. 35 U.S.C. § 112; see Carotek, Inc. v. Kobayashi Ventures, LLC, 875 F. Supp. 2d 313, 325-26 (S.D.N.Y. 2012). Failure to satisfy any of these requirements can result in the invalidation of an issued patent. See id.

#### **A. Written Description**

A patent's specification must describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112, ¶ 1. This written description requirement mandates that the specification "describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application." LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005).

The specification must thus demonstrate that "the inventor actually invented the invention claimed." Ariad Pharms., 598 F.3d at 1351. Whether "a skilled person could identify" or "envision" the invention is irrelevant; the question is "whether the application necessarily discloses that particular device." Goeddel v. Sugano, 617 F.3d 1350, 1355-56 (Fed. Cir. 2010) (internal quotation marks omitted). However, "the amount of detail that must be included in the specification depends on the

subject matter that is described and its role in the invention as a whole, in view of the existing knowledge in the field of the invention." Typhoon Touch Techs., Inc. v. Dell, Inc., 659 F.3d 1376, 1385 (Fed. Cir. 2011).

It is a question of fact whether a patent satisfies the written description requirement of paragraph 1 of section 112. See Ariad Pharm., 598 F.3d at 1355 (citing Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)). Any claim shown by clear and convincing evidence to be inadequately described is invalid. See ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1376 (Fed. Cir. 2009).

### **III. Statutory Bars to Patentability Under 35 U.S.C. § 102**

Section 102(b) of title 35 states that a person shall be entitled to a patent unless the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2006). These statutory bars prevent a patentee from placing her invention on sale or using it publicly before the "critical date," which occurs one year prior to the filing of the patent application. See Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1325 (Fed. Cir. 2009).

#### **A. Public Use**

As relevant here, section 102(b)'s bar on public use will invalidate a patent claim when, prior to the critical date, the claimed invention was in public use and ready for patenting. See Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379 (Fed. Cir. 2005). The subject of the alleged public use bar must meet each claim limitation of the invention. See Netscape Commc'ns Corp. v. Konrad, 295 F.3d 1315, 1323 (Fed. Cir. 2002).

The showing that an invention was "ready for patenting" before the critical date can be made in one of two ways: The moving party can prove either that an invention was "reduced to practice" or that the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. See Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67-68 (1998). An invention is reduced to practice when it works for its intended purpose, such that there is a demonstration of its workability or utility. See Atlanta Attachment Co. v. Leggett & Platt, Inc., 516 F.3d 1361, 1365 (Fed. Cir. 2008).

To decide whether a particular use is sufficiently public so as to be invalidating, courts ask "whether the purported use (1) was accessible to the public; or (2) was commercially exploited." Dey, L.P. v. Sunovion Pharm., Inc., 715 F.3d 1351, 1355 (Fed. Cir. 2013) (citing Invitrogen, 424 F.3d at 1380). In

addition, the Federal Circuit has set forth several factors that may be instructive in analyzing the question of public use, including "the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and commercial exploitation." See Invitrogen, 424 F.3d at 1380 (citing Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995)).

Whether the public use bar negates an otherwise valid patent claim is a question of law, based on underlying questions of fact. See Leader Techs., Inc. v. Facebook, Inc., 678 F.3d 1300, 1305 (Fed. Cir. 2012).

#### **i. Experimental Use**

While the public use bar protects the public by "discouraging the removal from the public domain of inventions that the public reasonably has come to believe are freely available," see Dey, 715 F.3d at 1355 (internal quotation marks and citation omitted), the public interest is also served when an inventor is given time to perfect his invention by public testing, see TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 968 (Fed. Cir. 1984). Consequently, evidence of experimental use, even if public, may negate application of the

public use bar to patentability. See EZ Dock, Inc. v. Schafer Sys., Inc., 276 F.3d 1347, 1352 (Fed. Cir. 2002).

A use is experimental if it is designed to "(1) test claimed features of the invention or (2) determine whether an invention will work well for its intended purpose." Clock Spring, 560 F.3d at 1326-27. The Federal Circuit has outlined certain objective factors that may be instructive when determining experimental use, including:

(1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Id. at 1327. By contrast, an inventor's expression of his own subjective intent to experiment, particularly after the institution of litigation, is generally of minimal value. See In re Smith, 714 F.2d 1127, 1135 (Fed. Cir. 1983).

Experimental use does not shift the burden of proof from the accused infringer to the patentee, as it is not an "exception" to public use. See id. at 1351-52. Instead, once a challenger of a patent has proven, by clear and convincing

evidence, that the invention was in public use before the critical date, the burden of production shifts to the patentee to provide sufficient evidence to create a genuine issue of material fact that the use qualifies as experimental. See id.; see also SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1317 (Fed. Cir. 2004). The burden of proof remains on the challenger to show that the non-experimental use was public under section 102(b).

#### **IV. Reissue Patent Requirements Under 35 U.S.C. § 251**

##### **A. Procedural Requirements**

Under the reissue statute, section 251 of title 35, a patent holder may seek reissue of an existing patent in certain circumstances. See 35 U.S.C. § 251. Specifically, the statute provides that:

Whenever [the] patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall . . . reissue the patent for the invention disclosed in the original patent. . . . No new matter shall be introduced into the application for reissue.

Id. Thus, a patent holder may file a reissue application to correct an error in the preparation or prosecution of a patent, so long as the error was made without any "deceptive intent."

See In re Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 522 (Fed. Cir. 2012).

In addition, sub-section (d) of section 251 provides that "[n]o reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." 35 U.S.C. § 251(d).

#### **B. The Rule Against Reissue Recapture**

It is well established, however, that a patentee may not "regain . . . through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims." In re Clement, 131 F.3d 1464, 1468 (Fed. Cir. 1997); see also Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 995 (Fed. Cir. 1993). Under this rule against recapture, "claims that are broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution are impermissible." Clement, 131 F.3d at 1468 (internal citation and quotation marks omitted).

Application of the recapture rule is a three step process: "(1) [F]irst, we determine whether, and in what respect, the reissue claims are broader in scope than the original patent claims; (2) next, we determine whether the broader aspects of the reissue claims related to subject matter surrendered in the

original prosecution; and (3) finally, we determine whether the reissue claims were materially narrowed in other respects, so that the claims may not have been enlarged, and hence avoid the recapture rule." N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1349 (Fed. Cir. 2005) (citing Clement, 131 F.3d at 1471).

In analyzing the third step in particular, it is important to distinguish among the original claims (i.e., the claims before the surrender), the patented claims (i.e., the claims allowed after surrender), and the reissue claims. There is no violation of the rule against recapture if the reissue claims "materially narrow" the claims relative to the original claims, such that full or substantial recapture of the subject matter surrendered during prosecution is avoided. See N. Am. Container, 415 F.3d at 1349.

Whether the claims of a reissue patent are invalid for violation of the recapture rule is a question of law. In re Mostafazadeh, 643 F.3d 1353, 1358 (Fed. Cir. 2011). Accordingly, reissue recapture is an issue often resolved on summary judgment. See, e.g., MBO Labs., Inc. v. Becton, Dickinson & Co., 602 F.2d 1306, 1312-19 (Fed. Cir. 2010); N. Am. Container, 415 F.3d at 1344-50.

#### **V. Validity of the '246 Patent**

### **A. Public Use**

Given that Small filed her initial application on January 30, 1995 (see '246 Patent, Murray Decl. Ex. 1, at 1), the critical date for the '246 Patent is January 30, 1994. Thus, in order to determine whether public use invalidates the '246 Patent, we must determine whether Small publicly used the invention claimed therein prior to January 30, 1994.

Nobel contends that the 1993 clinical procedure was a public use of an implant embodying Claims 14, 15 and 20 because it constituted a reduction of the invention to practice, rendering it ready for patenting, and because the patient was under no obligation to keep the modified implant confidential. (Nobel '246 Mem. at 5-6.) Small concedes that her claimed invention was ready for patenting prior to the critical date. Indeed, in her response to an interrogatory that the 1993 procedure evidenced her reduction to practice of the asserted claims, she acknowledged that the patient's slotted implant was ready for patenting upon completion of its modifications, which occurred in November 1993. (See Supp. Murray Decl. Ex. 2, at 7; see also Tr. at 166:8-10 (conceding that the '246 invention was reduced to practice before the critical date).) Rather, Small argues that the implant she modified in 1993 had become "stripped," or rounded, and therefore did not embody the

limitation requiring a "non-round" boss. (Pl. '246 Mem. at 14.) She further contends that the 1993 procedure constituted experimental use, thereby negating the application of the public use bar. (Id. at 8-9.)

As an initial matter, we conclude that the implant modified in 1993 embodied each of the asserted claim limitations. By Small's own admission, the claimed invention had been reduced to practice as of November 1993, when the custom-made crown was inserted in the patient's mouth and the implant, as modified, was deemed sufficient to serve its intended purpose. (Tr. at 166:8-10.) A reduction to practice requires that the invention meet the claim limitations and be known to work for its intended purpose. See In re Ceccarelli, 401 Fed. App'x 553, 555 (Fed. Cir. 2010) (citing Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1265 (Fed. Cir. 2002)). Thus, as a matter of law, she cannot both concede a reduction to practice and maintain that the implant did not embody the asserted claim limitations.

Further, as a matter of logic, a stripped hex does not cease to be a hex by virtue of becoming stripped; it remains fundamentally a hexagonally-shaped boss, despite the fact that some or all of its corners have become rounded due to damage exerted by rotational forces over time. Surely, Small would not

hesitate to assert her patent against an accused product simply because that product's boss had become stripped; to do so would undermine the '246 Patent's specification, which discloses a non-round boss with slots precisely because the boss possesses the tendency to become rounded. (See '246 Patent, Murray Decl. Ex. 1, at Col. 3:7-11.)

Having concluded that the implant modified in vivo met the limitations of the asserted claims, there can be no genuine dispute on the basis of the factual record before us that the 1993 clinical procedure was a public use.<sup>9</sup> In the course of performing the procedure, Small disclosed the claimed invention to other individuals, including her patient, the graduate student who assisted the procedure, and Leonard Marotta, the lab technician who created the custom crown.<sup>10</sup> The procedure was not conducted behind closed doors, but rather occurred at the N.Y.U. Clinic, "open to public observation without restriction[,]" which is sufficient to constitute public use." TP Labs., 724 F.2d at 969.

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<sup>9</sup> We note that the record cannot be supplemented with respect to Small's 1993 clinical procedure because the patient on whom it was performed has never been, and cannot be, identified. (See Tr. at 182:21-24.)

<sup>10</sup> We note that, for purposes of determining public use, the disclosure to Marotta is irrelevant under section 102(b) because Marotta was listed as a co-inventor on the '246 Patent application. See Clock Spring, 560 F.3d at 1325 ("An invention is in public use if it is shown to or used by an individual other than the inventor under no limitation, restriction, or obligation of confidentiality." (internal citation omitted)).

In addition, Small failed to impose confidentiality restrictions upon the individuals to whom she disclosed her invention. Her patient was under no such obligation, even during the period of several weeks in which the implant was exposed in the patient's mouth before Small attached the crown.<sup>11</sup> (See Small Dep., Murray Decl. Ex. 5, at 123:18-124:17.) Nor did Small require confidentiality from her student assistant or place restrictions on the photographic slides he took during the procedure. (See id. at 95:9-17.) The absence of restriction on the assistant, who was trained in oral surgery and could comprehend the significance of Small's slotted modification, particularly supports the conclusion that the use was public. "[I]f there is no confidentiality agreement in place, the skill and knowledge of those observing an invention can shed light on the degree to which it was kept confidential. Even limited disclosure to those who are skilled enough to know, understand, and easily demonstrate the invention to others, may mean that

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<sup>11</sup> Small's argument that the modified implant was not visible once the patient's gum was sewn closed is not to the contrary. Even if we were persuaded on the basis of the record before us that the implant remained invisible beneath the patient's gum, which we are not, the fact that an invention was hidden from view does not necessarily indicate that its use was not public. See TP Labs., 724 F.2d at 972 ("The fact that the device was not hidden from view may make the use not secret but non-secret use is not ipso facto public use activity. Nor, it must be added, is all secret use ipso facto not public use within the meaning of the statute, if the inventor is making commercial use of the invention under circumstances which preserve its secrecy." (internal quotation marks and citation omitted)). To the contrary, it is well established that the use of a claimed invention need not be open and visible to be considered public. See Am. Seating Co. v. USSC Group, Inc., 514 F.3d 1262, 1267 (Fed. Cir. 2008).

there was no reasonable expectation of secrecy and that the invention was therefore in public use." Dey, 715 F.3d at 1355-56 (internal quotation marks omitted); see also Netscape Commc'ns Corp. v. Konrad, 295 F.3d 1315, 1321 (Fed. Cir. 2002); Baxter, 88 F.3d at 1058 (invention was in public use when observers included "co-workers, who were under no duty to maintain . . . confidential[ity]").

Thus, we find that Small's 1993 disclosure of her invention without limitation or obligation of confidentiality rendered it sufficiently accessible to the public to warrant application of the public use bar. See Clock Spring, 560 F.3d at 1325 ("An invention is in public use if it is shown to or used by an individual other than the inventor under no limitation, restriction, or obligation of confidentiality.") (quoting Am. Seating Co., 514 F.3d at 1267). We therefore conclude that an invention embodying the asserted '246 Patent claims was in public use more than one year before Small filed her patent application, and hold that Claims 14, 15, and 20 of the '246 Patent are invalid as a result.

We further reject Small's argument that the 1993 clinical use was experimental in nature. Small has conceded that her invention was reduced to practice at least as early as November 1993. (Tr. at 166:8-10.) It is well established that

experimental use concludes upon an invention's reduction to practice. See EZ Dock, 276 F.3d at 1355 ("An invention could be the subject of an experimental use anytime up to reduction to practice."). Once reduced to practice, Small's invention could not have been the subject of an experiment that would negate a public use bar. See Atl. Thermoplastics Co. v. Faytex Corp., 5 F.3d 1477, 1480 (Fed. Cir. 1993).

Nevertheless, even assuming arguendo that the law supported Small's position, her 1993 procedure lacked the traditional indicia of formal experimentation sufficient to warrant negation of the public use bar. Small's patient was never informed that the procedure was experimental, nor was he asked to sign any additional paperwork beyond the standard forms required by the N.Y.U. dental clinic. (See Small Dep., Murray Decl. Ex. 3, at 104:6-25, 124:2-10, 126:6-22.). Indeed, the patient paid for the procedure according to N.Y.U.'s usual fee-for-services payment structure and while payment was not rendered specifically for the implant modification that became the subject of the '246 Patent (thus precluding a finding of commercial exploitation), it is clear that the patient understood the procedure to be within the normal course of his paid visit to the clinic.

Moreover, neither Small nor her assistant monitored the patient's implant over time to assess whether it was serving its intended purpose. Courts have often considered evidence of monitoring or further testing to determine whether a use was experimental, as it indicates that "the inventor[] . . . [was] working to detect and correct flaws in [the] invention." EZ Dock, 276 F.3d at 1353. Here, the patient visited Small only twice - first to have the implant repaired and then to have the crown attached. (See Small Dep., Murray Decl. Ex. 5, at 118:12-18.) Thus, there is simply no factual basis upon which we can conclude that the 1993 procedure constituted or was a part of a bona fide experiment.

#### **B. On Sale Bar**

Because we invalidate the '246 Patent on the grounds that the claimed invention was in public use more than one year before the critical date, we need not determine whether it was also on sale prior to that date.

#### **VI. Validity of the '945 Patent**

With respect to the validity of the '945 Patent, Nobel advances two arguments. First, it argues that the asserted claims, which all depend from independent Claim 14 and therefore include the recess and "part way down" slot depth limitations of that claim, are invalid for lack of adequate written

description. (Nobel '945 Mem. at 15-17.) It further submits that the asserted claims violate the rule against reissue recapture. (Id. at 20-26.) For the reasons that follow, we find that each argument states an independent ground for invalidation of the asserted claims.

#### **A. Written Description**

Nobel first contends that the asserted claims are unsupported by the '945 Patent's specification, given that the specification fails to show or describe a slot that extends part way down a recess, rendering them invalid for failing to satisfy the written description requirement of section 112. (Nobel '945 Mem. at 17.) It submits that the specification's disclosure of a broad range of possible slot depths provides insufficient written support for a specific depth limitation.

In response, Small argues that she can claim slots which extend "part way down" as a limitation to her invention because a person of ordinary skill in the art would understand her description of slots of "various depths" to include any specific slot depth within the range of all possible depths. (See Pl. '945 Opp. at 6.) However, that argument relies on the logical fallacy that to disclaim nothing is to claim everything. Patent law requires far more to support a claim of adequate written description. See New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.,

298 F.3d 1290, 1295 (Fed. Cir. 2002) ("The purpose of the written description requirement is broader than to merely explain how to make and use; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. That is, the disclosure must show he had invented each feature that is included as a claim limitation.") (internal quotation marks and citation omitted). In other words, it is not sufficient that Small used language broad enough to encompass any potential slot depth; she must have indicated to the reasonably skilled observer that slot depth was a claimed feature of her invention.

Applying that standard here, we are not persuaded that the '945 Patent's specification indicates Small's possession of the part way down feature. Nothing in the specification's language or drawings even intimates to a person of ordinary skill in the art that Small was claiming use of the depth of slots down the side surfaces of the recess. Had Small wanted to claim slot depth as a feature of her invention, she could have specified a minimum or maximum depth or a range of depths in accordance with which her implant was to be manufactured. Instead, while the written description mentions slot depth three times, none of those mentions suggests that Small invented a slot of any

particular depth. (See 1996 Application, Murray Decl. Ex. 7, at 27:6-11, 28:3-6, 16-19.) Merely stating that the slot may penetrate the boss or recess "to various depths" does not indicate that a specific depth within the range of all possible depths might act as a limitation on the invention claimed. As we read the '945 Patent's specification, slot depth was irrelevant to Small's invention.<sup>12</sup>

That conclusion is supported by language in the specification itself, which states that the implant is "penetrated by slots . . . of extended length and selectable (in manufacture) depth." (Murray Decl. Ex. 7, at 28:17-19.) In so describing the depth of the slots, Small affirmatively indicated to the public that depth was a malleable feature to be chosen by the manufacturer of the implant, and not one that she had chosen herself. See New Railhead Mfg., 298 F.3d at 1295 (concluding that a "disclosure must show [the inventor] had invented each feature that is included as a claim limitation"). To permit her

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<sup>12</sup> In her opposition brief, Small misinterprets Nobel's argument to rely on the fact that she "did not explain the importance of the depth of the slots." (Pl. '945 Opp. at 8.) However, Small overlooks the conclusion at which we now arrive, which is that she did not disclose slot depth as a feature of her invention in a way that "reasonably conveys to those skilled in the art" that she "had possession of the claimed subject matter as of the filing date." Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed Cir. 2010) (en banc). We agree with Small that there is no legal requirement that a patent specification explain or convey the technical importance of a claimed feature of an invention. See Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004). The problem is not that the '945 Patent's specification fails to explain the advantage of a particular slot depth, but that it does not convey, either explicitly or implicitly, the use of slot depth as a feature of her invention.

to claim ownership of a particular slot depth would be to contradict the very written description on which she relies.

Our conclusion also comports with the historical development of Small's claimed invention. By her own account, Small was not at all concerned with slot depth during the 1993 clinical procedure upon which her initial patent application relied. She did not measure the slots as she was drilling them into her patient's implant, nor did she conduct testing to determine the optimal depth or range of depths. (See Small Dep., Murray Decl. Ex. 5, at 101:18-24.) Indeed, at her deposition, Small testified that she was not trying to achieve any particular slot depth, as evidenced by her observation that she had drilled one slot further down into the patient's implant than the other. (See id. at 100:2-3, 17-19.)

Furthermore, the idea to disclose slots which extend "part way down" the recess walls did not originate with Small, but was a strategy suggested by the patent examiner during reissue to evade the prior art. (Bugg Decl. Ex. 3, at 2-3; see Pl. '945 Opp. at 6; Tr. at 31:16-32:3.) That Small did not conceive of the part way down slot limitation herself provides further support for the conclusion that she did not intend to claim slot depth as a feature of her invention until her 2004 amendment of the proposed reissue claims.

Notably, Small could have amended the '590 Patent's specification during the prosecution of her reissue patent to accommodate her addition of the "part way down" feature. However, doing so would have added "new matter" to the specification, thereby denying her the benefit of the original 1995 application date. See Anascape, Ltd. v. Nintendo of Am. Inc., 601 F.3d 1333, 1337 (Fed. Cir. 2010) ("For a parent application to provide the filing date for claims of a continuing application, the description in the parent must meet the requirements of 35 U.S.C. § 112, first paragraph, as to that claimed subject matter."). Small needed to claim priority to the 1995 filing date in order to avoid infringing Nobel's '291 Patent, which was filed in 1999, and assert her recessed claims against Nobel's Replace Select implant. Given the timing of Small's filing of her infringement suit against Nobel, i.e., within six days of the reissue of her patent, one can only conclude that she made a deliberate decision to keep the specification as is - one that is ultimately fatal to the claims asserted here.

Because no reasonable juror could find that the original disclosure was sufficient to enable one of skill in the art to recognize that Small invented slots which extend "only part way down" the side surfaces of the recess, we find that Claims 14-20

and 22 are invalid for failing to satisfy the written description requirement.

**B. Recapture of Surrendered Subject Matter in Reissue Patent**

While the above discussion constitutes sufficient grounds to invalidate the asserted claims of Small's '945 Patent, we nevertheless address Nobel's argument regarding reissue recapture. Nobel maintains that Small surrendered the asserted recessed claims when she cancelled her original recessed claims during prosecution of the '590 Patent. As a result, it submits, the law of reissue bars Small from asserting the reissue claims in this action. (Nobel '945 Mem. at 20.) Small asserts that the law of reissue recapture does not apply because her reissue recessed claims are materially narrower than the claims cancelled during the original prosecution. (Pl. '945 Opp. at 15.)

As stated above, 35 U.S.C. § 251 provides for the reissue of a patent:

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent, . . . reissue the patent . . . for the unexpired part of the term of the original patent.

35 U.S.C. § 251. It is undisputed that a reissue patent may be broader than the patent as originally filed. Further, the statute provides that "[n]o reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." Id. § 251(d). Because the '590 Patent issued on September 23, 1998, the two-year period in which Small could have filed a broadening reissue application expired on September 23, 2000.

We find that Small failed to comply with the requirements of section 251 both procedurally and substantively. Small correctly observes that she filed her reissue application on September 22, 2000. However, it was not until three years later, following repeated notices informing her that her application lacked a supporting declaration, that she provided an explanation of the error upon which her reissue application was based. (See October 22, 2003 Response to Office Action, Murray Decl. Ex. 10, at 5.) It is noteworthy that the reissue application itself makes perfectly clear what is required for a reissue filing: "If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening." (Murray Decl. Ex. 11, at 1.) Nonetheless, Small submitted no such explanatory statement to support her

broadening claims within the two-year period set forth in § 251(d).

Further, the error Small finally identified in her October 22, 2003 response was a "[f]ailure to broadly claim the 'boss' as set forth in claim 15." (Murray Decl. Ex. 11, at 1.) Thus, as initially proposed in 2003, her broadening claims were exclusively directed to bossed implants. (Id.) It was not until October 28, 2004, more than six years after her initial patent application and well beyond the two-year period, that Small filed an amendment to her reissue application seeking further broadening in the form of claims directed to a recessed implant. (See Murray Decl. Ex. 12, at 2.) The history of Small's reissue makes clear that she wholly failed to comply with the requirements of § 251 because she neither submitted her initial broadening claims within the two-year statutory period, nor identified a remediable error to support her recessed claims.<sup>13</sup>

This conclusion in no way undermines the broad proposition that an applicant who files a reissue application within two

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<sup>13</sup> Notably, Small submitted no supplemental statement of error in support of her amended broadening claims. (See id. at 4 (noting that "a Supplemental Re-issue Application Declaration signed by the inventors will be filed shortly").) At oral argument, counsel for Small told the Court that the error upon which Small relied in amending her reissue application to include recessed claims was that she had previously "claimed less than [she] had to" in the '590 Patent. (Tr. at 108:11-13.) We find no support for that statement in the record.

years may make additional broadening amendments, even after the two-year window has closed, as reflected in recent Federal Circuit decisions such as In re Staats and In re Youman. See, e.g., In re Staats, 671 F.3d 1350, 1355 (Fed. Cir. 2012); In re Youman, 679 F.3d 1335, 1345 (Fed. Cir. 2012). In those cases, the question presented was whether claims that are not submitted until more than two years after the grant of the original patent, and which are broader in scope than both the original patent claims and the broadening reissue claims originally submitted, are barred by § 251. See Staats, 671 F.3d at 1353.

By contrast, this case presents an atypical, if not unique, set of facts.<sup>14</sup> Small's 2004 amendment achieved more than a simple expansion of her initial broadening claims. Rather, it added claims containing the same subject matter that she had deliberately cancelled in 1998, thereby undermining congressional intent to strictly limit the availability of reissue patents to instances in which the patentee could demonstrate an "error without any deceptive intention." See 35 U.S.C. § 251. The Federal Circuit has interpreted such "error" to require inadvertence on the part of the patentee, such as where the patentee unintentionally claimed less subject matter

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<sup>14</sup> While our research has not revealed another case with parallel facts to this one, that may simply be because no one else has abandoned claims to obtain a patent and returned six years later, after others have entered the market, to reassert the long-abandoned claims.

than she had a right to claim. See MBO Labs., 602 F.3d at 1313 ("This court bars recapture because a patentee is only entitled to a reissue patent for broader claims when the patentee claimed less than he had a right to claim in the patent through error without any deceptive intent [], not through deliberate amendments or arguments designed to convince an examiner to allow the claims.") (internal quotation marks omitted); Medtronic, Inc. v. Guidant Corp., 465 F.3d 1360, 1372-73 (Fed. Cir. 2006). Here, the '590 Patent's exclusive direction to bossed implants was not the result of a failure to appreciate the full scope of Small's invention. It reflected a deliberate decision made to ensure the issuance of the '590 Patent despite the prior art. There was simply no inadvertence attendant to Small's cancellation of her recessed claims.

Moreover, the Federal Circuit prohibits recapture in such circumstances based on principles of equity. A patentee's surrender of subject matter places "competitors and the public . . . on notice . . . and may [cause them] to rely on the consequent limitations on claim scope." MBO Labs., 474 F.3d at 1331. As late as October 21, 2003, the public prosecution record conveyed neither that Small was entitled to a patent describing a recessed implant, nor that she was interested in pursuing one. In the interim between Small's abandonment of her

recessed claims in 1998 and her reassertion of such claims in 2004, Nobel invested a considerable amount of time and effort into the development and market entry of its Replace Select implant. In so doing, Nobel was fully justified in relying on the public record, which contained no forewarning that Small intended to claim entitlement to a recessed implant, let alone one with slots which extend only "part way down" the recess walls. See Vectra Fitness, Inc. v. TNWK Corp., 162 F.3d 1379, 1384 (Fed. Cir. 1998) ("[T]he recapture rule . . . ensur[es] the ability of the public to rely on a patent's public record.") (internal quotation marks omitted); see also Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 993 (Fed. Cir. 1993) ("[T]he reissue statute cannot be construed in such a way that competitors, properly relying on prosecution history, become patent infringers when they do so."). To permit the asserted claims to stand would sanction the flouting of the public notice function of § 251.

#### **VII. Infringement of the '945 Patent**

Because we invalidate the '945 Patent claims asserted against Nobel and Implant Direct, Implant Direct cannot, as a matter of law, infringe those claims. See Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc., 714 F.3d 1289, 1295 (Fed. Cir. 2013) ("[N]o accused products can be found liable for

infringement of an invalid claim." ). We therefore grant Implant Direct's motion for summary judgment as to its non-infringement.

#### **CONCLUSION**

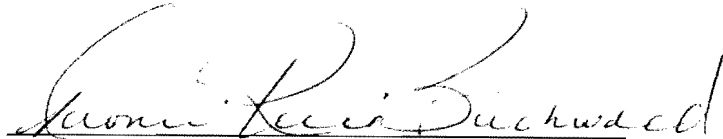
Timing is important. The reward for being first to patent an invention is great, which explains why strict limitations govern a patentee's ability to recast her patent claims while retaining the benefit of the original filing date. At every stage of prosecution, Small has waited until the last possible moment - or later - to continue, amend, and seek reissue of her patents. She was late in filing her '246 Patent application, given that she had used her invention publicly more than one year before filing her application. She waited until the last possible date to apply for reissue, and was inexcusably late in seeking to amend that reissue application to include claims to a recessed implant. The law should not reward those who sleep on their rights, particularly when protecting a privilege as exclusive as a United States patent. Moreover, when an applicant delays in asserting a claim, the law should protect those who justifiably rely on the public record when investing in the development of new inventions.

Thus, for the aforementioned reasons, we grant Nobel's motion for summary judgment of the invalidity of Claims 11, 14, and 15 of the '246 Patent. We further grant Nobel's motion for

summary judgment of the invalidity of Claims 14-20 and 22 of the '945 Patent. Finally, we grant Implant Direct's motion for summary judgment due to non-infringement of the asserted '945 Patent claims. The Clerk of the Court is hereby directed to terminate the motions pending at docket numbers 276, 279, 285, 286 and 292 and close these cases.

**SO ORDERED.**

DATED: New York, New York  
August 1, 2013

  
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NAOMI REICE BUCHWALD  
UNITED STATES DISTRICT JUDGE

Copies of the foregoing Order have been mailed on this date to the following:

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